



**AMERICAN VETERINARY MEDICAL ASSOCIATION**

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4590 '99 SEP 21 THU 25

September 13, 1999

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**RE: DOCKET NUMBERS 98N-1230, 96P-0418, and 97P-0197**

Dear Sir or Madam:

The American Veterinary Medical Association supports the proposal to require safe handling statements on labels of shell eggs that have not been treated to destroy *Salmonella* microorganisms. We also support the proposal to require refrigeration of shell eggs when stored and displayed in retail establishments. We agree that these measures will improve public health.

However, we disagree with the proposed wording of the safe handling instructions. Because the prevalence of *Salmonella* in shell eggs is less than the prevalence in meat and poultry products, the safe handling instructions for shell eggs need not be more alarmist than the safe handling labels on meat and poultry products.

The background to the proposed rule attempts to justify the need for a strongly worded instruction by presenting consumption data indicating that some consumers eat raw or undercooked eggs which is assumed as support to the FDA conclusion that consumers may not know that there is a food safety hazard associated with shell eggs. It is difficult to believe, after 12 years of news media stories and educational efforts by the USDA, FDA, and consumer groups about the dangers of shell eggs, that consumers are not knowledgeable. Before implementing a strongly worded safe handling instruction, the FDA should determine whether consumers are indeed uninformed or whether they choose to ignore the knowledge that they possess.

Another weakness with the FDA conclusion is that it is based on the assumption that a lack of knowledge by consumers is proven by the continued predominance of SE in foodborne outbreaks. Most outbreaks result from food service workers, not the individual consumer, who mishandle shell eggs by pooling many eggs and then storing the pooled eggs at temperatures greater than 45°F. Warning statements on cartons of eggs, or on shipping invoices, are not going to change the behavior of food service workers who take shortcuts to make their job easier. Improved enforcement is needed to correct this problem. Additionally, the FDA conclusion which is based on the continued predominance of SE in foodborne outbreaks is further weakened by the recent data from FoodNet. As reported in the proposal background, there has been a 44% decrease in

the isolation rate for SE from 1996 to 1998. FoodNet also reported that in 1998 only 15% of the *Salmonella* isolates that were serotyped were serotype Enteritidis. Thirty percent were serotype Typhimurium. While the rate of infections caused by all serotypes of *Salmonella* decreased by 14% from 1996 to 1998, the rate for SE declined by 44%. So there are reasons that are unique to SE for the additional decline. Consumer awareness may be one of the reasons. It is true as stated in the background that these results are reported as preliminary data but that is only because the incidence rates were calculated using 1997 population estimates. The final incidence will be available once 1998 population estimates are available. It is expected that use of the 1998 population estimates will further reduce the incidence because of the growth in the population between 1997 and 1998. Other data, such as that from the CDC National Antimicrobial Resistance Monitoring System: Enteric Bacteria, confirm the decreasing predominance of SE. Between 1996 and 1998, the proportion of *Salmonella* isolates that were serotyped as SE decreased from 27% to 17%, while serotype Typhimurium increased from 23% to 26%.

We propose that, while safe handling instructions are necessary for shell eggs, the instructions should not offer more warning than that supplied by the safe handling instructions on meat and poultry products. Further, to minimize consumer confusion, the statements should be as similar as is appropriate to the differences in food products. We propose that the following statement be considered:

**SAFE HANDLING INSTRUCTIONS;** Eggs may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, keep eggs refrigerated and cook thoroughly.

We appreciate the opportunity to comment.

Sincerely,

A handwritten signature in cursive script that reads "Bruce W. Little".

Bruce W. Little, DVM  
Executive Vice President

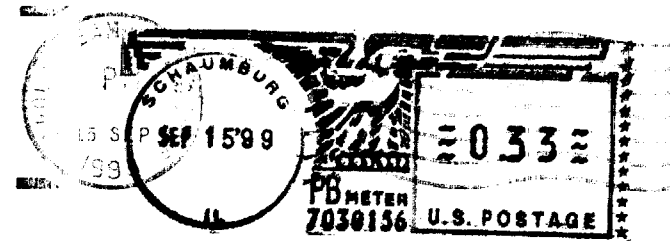
CPHRVM/LPV

HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION  
**CROSS REFERENCE SHEET**

Docket Number/Item Code: 98N-1230/C641

See Docket Number/Item Code: 97P-0197/C642  
96P-0418/C641

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